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| 10/780,339 | 02/17/2004 | Hyesook Kim | 3087.00013 | 1112 |
| 48924 7590 07/26/2007 KOHN & ASSOCIATES, PLLC 30500 NORTHWESTERN HWY STE 410 FARMINGTON HILLS, MI 48334 | | | | |
| | | | EXAMINER DUNSTON, JENNIFER ANN | |
| | | | ART UNIT 1636 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/780,339

Applicant(s)

KIM ET AL.

Examiner

Jennifer Dunston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 22-25 and 32-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 May 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the amendment, filed 5/3/2007, in which claims 1, 7, 16 and 26 were amended. Currently, claims 1-34 are pending.

Applicant's arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn. **This action is FINAL.**

Election/Restrictions

Applicant elected Group I (claims 1-21 and 26-31) with traverse in the reply filed on 10/10/2006.

Claims 22-25 and 32-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/10/2006.

This application contains claims 22-25 and 32-34 drawn to an invention nonelected with traverse in the reply filed 10/10/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Currently, claims 1-21 and 26-31 are under consideration.

Response to Arguments - Double Patenting

The rejection of claims 16 and 17 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8-9 and 12-13 of copending Application No. 10/593,412 has been withdrawn in view of Applicant's amendment to the claims in the reply filed 5/3/2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is a new rejection, necessitated by the amendment of claim 7 to include the phrase "further including control means for identifying and characterizing the chemical."

Claim 7 is vague and indefinite in that the metes and bounds of the phrase "control means for identifying and characterizing the chemical" are unclear. The recitation, "control means for identifying and characterizing the chemical" meets the three prong analysis of 112, 6th paragraph set forth in MPEP 2181, section I. The specification does not explicitly describe a "control means." It is unclear if the means has a controlling function or an "identifying and characterizing" function. Thus, one skilled in the art would not be able to identify the structure of the control means from the description in the specification for performing the recited function.

Claims 8-15 depend from claim 7 and thus are indefinite for the same reasons as applied to claim 7.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new rejection, necessitated by the amendment of claim 7 to include the phrase "further including control means for identifying and characterizing the chemical."

The claims are drawn to a device comprising a "control means for identifying and characterizing" a chemical. The recitation, "control means for identifying and characterizing the chemical" meets the three prong analysis of 112, 6th paragraph set forth in MPEP 2181, section I.

The specification does not explicitly describe a "control means." It is unclear if the means has a controlling function or an "identifying and characterizing" function. Thus, one skilled in the art would not be able to identify the structure of the control means from the description in the specification for performing the recited function.

Claims 7-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

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invention. **This is a new matter rejection.** This is a new rejection, necessitated by the amendment of claim 7 to include the phrase “further including control means for identifying and characterizing the chemical.”

The claims are drawn to a device comprising a “control means for identifying and characterizing” a chemical. The recitation, “control means for identifying and characterizing the chemical” meets the three prong analysis of 112, 6th paragraph set forth in MPEP 2181, section I.

The specification does not explicitly describe a “control means.” It is unclear if the means has a controlling function or an “identifying and characterizing” function. Thus, one skilled in the art would not be able to identify the structure of the control means from the description in the specification for performing the recited function.

The response does not point to portions of the originally filed specification that provide support for the claimed control means for identifying and characterizing a chemical. A thorough search of the specification, as filed, did not identify literal or inherent support for the structures capable of performing the claimed function. The specification does not teach structures capable of identifying a chemical. The detecting means for detecting changes in gene expression could also be considered a means for characterizing a chemical in that it can characterize changes in gene expression in response to a chemical; however, the specification does not provide support for a device comprising a detecting means and a control means.

Accordingly, the amendment is a departure from the specification and claims as originally filed.

Response to Arguments - 35 USC § 112

The previous rejection of claims 1-15 and 26-31 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's amendment to the claims in the reply filed 5/3/2007.

The previous rejection of claims 1-15 and 26-31 under 35 U.S.C. 112, first paragraph (scope of enablement) has been withdrawn in view of Applicant's amendment to the claims in the reply filed 5/3/2007).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-21 and 26-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Altmann et al (Developmental Biology, Vol. 236, pages 64-75, 2001, cited in a prior action; see the entire reference). This rejection was made in the Office action mailed 1/3/2007 and has been rewritten to address the amendments to the claims in the reply filed 5/3/2007.

Claims 1-15 and 26-29 are drawn to "a screen." The instant specification defines the term "screen" to be any device capable of screening for gene expression in an embryo (page 8, lines 11-13). Regarding the claimed "detecting means for detecting changes in gene expression," the instant specification discloses a microarray as such means (e.g., page 14).

Regarding claims 1-6 and 16-21, Altmann et al teach a microarray comprising cDNA sequences obtained from a *Xenopus* early gastrula library (e.g. Title; page 65, clone preparation, and prototype microarray preparation; pages 67-68, Scanning and Data Analysis; page 69, left column, 2nd full paragraph). Altmann et al teach that the microarray is capable of detecting gene expression of embryos prior to the onset of zygotic transcription (e.g. page 69, left column, 2nd full paragraph). Accordingly, the microarray of Altmann et al is contains probes for hybridizing to RNA generated from chemically treated animal cleavage stage embryos, which are embryos that have not begun zygotic transcription.

Regarding claims 7-15, Altmann et al teach a microarray comprising cDNA sequences obtained from a *Xenopus* early gastrula library (e.g. Title; page 65, clone preparation, and prototype microarray preparation; pages 67-68, Scanning and Data Analysis; page 69, left column, 2nd full paragraph). Altmann et al teach that the microarray is capable of detecting gene expression of embryos prior to the onset of zygotic transcription (e.g. page 69, left column, 2nd full paragraph). Accordingly, the microarray of Altmann et al is contains probes for hybridizing to RNA generated from chemically treated animal cleavage stage embryos, which are embryos that have not begun zygotic transcription. The metes and bounds of the phrase “control means for identifying and characterizing the chemical” are unclear (see the rejection under 35 U.S.C. 112, second paragraph, set forth above). For the purposes of this rejection, the phrase has been interpreted as a structure that is a control probe on the microarray. Altmann et al teach that each of the probes can be used as a control by repeating hybridization experiments to determine the variability in the hybridization signal (e.g., page 69, right column, first full paragraph).

Regarding claims 26-31, Altmann et al teach a microarray comprising cDNA sequences obtained from a *Xenopus* early gastrula library (e.g. Title; page 65, clone preparation, and prototype microarray preparation; pages 67-68, Scanning and Data Analysis; page 69, left column, 2nd full paragraph). Altmann et al teach that the majority of the genes on the microarray are expressed both prior to zygotic transcription and after zygotic transcription at the gastrula stage (e.g., page 69, Application of the Prototype Microarray in Temporal Assays). At least some of the genes will also be expressed at the neurulation stage (e.g., Figure 3). Thus, the microarray of Altmann et al contains probes for hybridizing RNA probes generated from chemically treated animal neurulation stage embryos.

Claims 1-21 and 26-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Hemmati-Brivanlou et al (US Patent Application Publication No. 2002/0081610 A1, cited in a prior action; see the entire reference). This rejection was made in the Office action mailed 1/3/2007 and has been rewritten to address the amendments to the claims in the reply filed 5/3/2007.

Claims 1-15 and 26-29 are drawn to "a screen." The instant specification defines the term "screen" to be any device capable of screening for gene expression in an embryo (page 8, lines 11-13). The specification provides microarray as an example. Claims 7-15 are specifically drawn to a microarray screen (i.e., microarray device). Regarding the "detecting means for detecting changes in gene expression" of claims 1-6, the instant specification discloses a microarray as such means (e.g., page 14).

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Regarding claims 1-6 and 16-21, Hemmati-Brivanlou et al teach microarrays containing *Xenopus laevis* embryonic gene sequences (e.g. Abstract; paragraphs [0006], [0066]-[0083]). Hemmati-Brivanlou et al teach a microarray comprising 768 clones, some of which are capable of hybridizing to mRNA isolated from cleavage stage embryos (stage 6) (e.g., paragraphs [0119] and [0121]). Accordingly, the microarray of Hemmati-Brivanlou et al is a means for detecting changes in gene expression of cleavage stage embryos.

Regarding claims 7-15, Hemmati-Brivanlou et al teach microarrays containing *Xenopus laevis* embryonic gene sequences (e.g. Abstract; paragraphs [0006], [0066]-[0083]). Hemmati-Brivanlou et al teach a microarray comprising 768 clones, some of which are capable of hybridizing to mRNA isolated from cleavage stage embryos (stage 6) (e.g., paragraphs [0119] and [0121]). Accordingly, the microarray of Hemmati-Brivanlou et al is a means for detecting changes in gene expression of cleavage stage embryos. The metes and bounds of the phrase “control means for identifying and characterizing the chemical” are unclear (see the rejection under 35 U.S.C. 112, second paragraph, set forth above). For the purposes of this rejection, the phrase has been interpreted as a structure that is a control probe on the microarray. Hemmati-Brivanlou et al teach the inclusion of negative control probes to demonstrate that hybridization is specific to the test probes (e.g., paragraph [0084]).

Regarding claims 26-31, Hemmati-Brivanlou et al teach microarrays containing *Xenopus laevis* embryonic gene sequences (e.g. Abstract; paragraphs [0006], [0066]-[0083]). Hemmati-Brivanlou et al teach a microarray comprising 768 clones, some of which are capable of hybridizing to mRNA isolated from neurulation stage embryos (e.g., paragraphs [0119] and

[0121]; Figure 2). Accordingly, the microarray of Hemmati-Brivanlou et al is a means for detecting changes in gene expression of neurulation stage embryos.

Response to Arguments - 35 USC § 102

With respect to the rejection of claims 1-21 and 26-31 under 35 U.S.C. 102(b) as being anticipated by Altmann et al, Applicant's arguments filed 5/3/2007 have been fully considered but they are not persuasive.

The response essentially asserts that the presently amended claims require a detecting means that requires an animal cleavage stage embryo hybridization means, and Altmann et al do not teach such a means. The response asserts the cleavage stage embryo contains only gene products (mRNA) inherited from the mother. The response notes that cleavage stage embryos are both at pre-stage 4 and stage 8. The response acknowledges that Altmann et al teach the hybridization of mRNA obtained from embryos prior to the onset of zygotic transcription at stage 6 to the disclosed microarray.

The instant claims are drawn to a product. The detection means or hybridization means disclosed in the instant specification is a microarray (e.g., page 14). Altmann et al teach a microarray comprising probes capable of hybridizing to an embryo at stage 6 (a cleavage stage embryo according to the response; i.e., an embryo prior to stage 8). Thus, Altmann et al teach a structure that meets each of the limitations of the rejected claims.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

With respect to the rejection of claims 1-21 and 26-31 under 35 U.S.C. 102(e) as being anticipated by Hemmati-Brivanlou et al, Applicant's arguments filed 5/3/2007 have been fully considered but they are not persuasive.

The response asserts that Hemmati-Brivanlou et al are concerned with gene expression changes that occur after gastrulation and not at the cleavage stage. This is not found persuasive, because the instant claims are drawn to a product rather than a method. The microarray structure of Hemmati-Brivanlou et al is capable of detecting gene expression in cleavage stage embryos (e.g., paragraphs [0119] and [0121]).

The remarks made regarding the Altmann et al rejection have been considered with respect to the Hemmati-Brivanlou et al rejection but are not found persuasive. The microarray structure of Hemmati-Brivanlou et al is capable of detecting gene expression in cleavage stage embryos (e.g., paragraphs [0119] and [0121]). The structure of Hemmati-Brivanlou et al meets each of the limitations of the rejected claims.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

The previous rejection of claims 7-9 and 13-15 under 35 U.S.C. 102(b) as being anticipated by Herwig et al has been withdrawn. The arguments directed to the Herwig reference are considered moot in view of the new rejections made over the Altmann et al and Hemmati-Brivanlou et al references presented above.

Conclusion

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

/JD/

CELINE QIAN, Ph.D.
PRIMARY EXAMINER

